

**Tennessee Medical Laboratory Board Meeting
July 15, 2010
Minutes**

Date: July 15, 2010

Time: 9:00 AM CDT

Location: Bureau of Health Licensure and Regulation
TN Department of Health
Heritage Place Iris Room
227 French Landing, Ground Floor
Nashville, TN 37243

Members Present: Norman Crowe, Chairman, Independent Lab Manager
Edward McDonald, MD Pathologist, Vice-Chairman
Trudy Papuchis, MD Pathologist Hospital Administrator
Pamela Bullock, MD Non-educator Pathologist
Royce Joyner, MD, Pathologist Educator
Darius Y. Wilson, MAT, Ed.D. Educator
Cheryl Arnott, S.A.-Cytotechnologist
Gloria Jenkins, Citizen Representative

Members Absent: Annie Washington, Medical Technologist
Diane Robbins, Medical Technologist
Christopher H. Seay, Medical Technologist
Non Pathologist Physician (Position Vacant)
Hospital Administrator (Position Vacant)

Staff Present: Lynda S. England, Medical Technologist Consultant,
Director, TMLB
Jerry A. Gowen, Medical Technologist Consultant
Diona Layden, Assistant General Counsel, Advisory
Attorney
Elizabeth Miller, Director-Health Related Boards
Julia Daniels, Medical Technologist Consultant/
Surveyor, East Tennessee Regional Office
Taylor Carpenter, Medical Technologist
Consultant/Surveyor, East Tennessee Regional Office
Onezean Otey, Jr., Medical Technologist
Consultant/Surveyor, Middle Tennessee Regional Office
Karen Hargrove, Medical Technologist,
Consultant/Surveyor, Middle Tennessee Regional Office
Mary Hamblen, Medical Technologist
Consultant/Surveyor, West Tennessee Regional Office

Staff Absent: Karon Hathcoat, Medical Technologist Consultant/
Surveyor, West Tennessee Regional Office

CLIA Representative: Sandra Bogard, CLIA Manager

**Minutes
Medical Laboratory Board
July 15, 2010**

Quorum: A sufficient number of board members were present to constitute a quorum

Call To Order: The meeting was called to order at 9:03 AM CDT by Mr. Crowe.

Presiding Officer: The meeting was conducted by Mr. Crowe

Introductions: Board and Staff made their introductions to the public in attendance

Amendment to the Agenda: None were presented

Approve Minutes:

P & E A motion to approve the April 14, 2010 Personnel & Education Committee minutes was made by: Dr. McDonald
Second: Dr. Wilson

Motion approved

Board The minutes from the April 15, 2010 board meeting were approved on a motion made by: Dr. McDonald
Second: Dr. Joyner

Motion approved

Board Reports:

Ratification of P&E Committee Minutes: Mr. Crowe reported on the actions of the Board's Personnel & Education Committee meeting, July 14, 2010.

There was discussion and clarification regarding the Initial MedVance Training program for MLT students in Nashville.

Motion: Dr. Papuchis
Second: Dr. McDonald

The report was ratified as given.

Contested Cases No contested cases were presented during this meeting.

**Consent, Agreed,
Compliance Orders**

Consent

The consent order was reviewed by the Board.

(Dr. Joyner recused himself. Quorum maintained.)

Ronald Lessard
Medical Laboratory Technologist-Supervisor
License # 8338

Move to suspend license for failure to comply with a
previous consent order to complete TnPAP program:

Dr. McDonald

Second: Ms. Jenkins

Consent Order approved.

Agreed

There were no agreed orders presented during this
meeting.

Compliance

An order of compliance was reviewed by the Board.

Cynthia D. McNutt
Medical Laboratory Technologist-General
License#19798

Ms. McNutt completed her consent order requirements.

Motion to ratify the Order: Dr. McDonald

Second: Dr. Papuchis

Motion to ratify the Order approved.

**Letters of
Reprimand**

There were no letters of reprimand presented during this
meeting.

**Tennessee Professional
Peer Assistance Program
(TNPAP):**

The report was given by Mike Harkreader, MA, RN *
TNPAP State Director.

The TNPAP statistical report for the period July 1, 2009
To June 30, 2010, stated this advocacy agency was
currently monitoring four (4) individuals.

During this period there were five (5) referrals. Referral
sources, Board four (4) and Other one (1). Reasons for
referral one (1) Alcohol; two (2) History of Arrest; one
(1) Forgery; one (1) + UDS Workplace. Four (4)
individual signed a monitoring agreement and one (1)
individual did not need a monitoring agreement.

Discharges, six (6) individual successfully completed
their monitoring agreement, one (1) monitoring not

necessary and One (1) individual that was non-compliant, could not come into compliance and was reported to the Department of Health.

Mr. Harkreader spoke that the Board should be diligent when it comes to disciplinary action, the extent of the actions taken against licenses and the time it takes to respond.

Note: Review of TNPAP materials via internet counts as clock hours toward continuing education credits. A certificate of completion documenting review of these materials can be completed at the end of the internet session. Internet site: www.TNPAP.org

Ratifications: The following items were presented to board members for ratification per staff, state surveyor or facility request:

Exemptions for point of care testing procedures (POCT) in a licensed Facility

**Baptist Memorial
Memphis, TN**

(Dr. Wilson recused herself)

Teresa Hippell, Laboratory Manager, made a new request to for exemption to allow registered respiratory therapists to perform lactate testing in the emergency department and critical care areas using the GEM 4000.

Motion to approve: Dr. Papuchis

Second: Dr. Bullock

Motion approved.

**Memorial
Northpark
Hixson, TN**

Ann Durham, MT, supervisor of POCT, requested an initial exemption to allow Respiratory Therapist to use the I-Stat on the Code Team, Rapid Response Team and in the Emergency Department, for Chem 8 cartridge testing.

There were questions during the April, 2010 meeting regarding correlation studies. Ms. Durham presented current correlation studies as a result of those questions.

Motion to approve: Dr. Bullock

Second: Dr. McDonald

Motion approved

**Skyline Medical
Center
Nashville, TN**

Sherry Masemer, POC Coordinator, requested an initial exemption to allow RNs in the OR and Nursing Supervisors at the Madison Campus to perform and report testing results using the I-Stat meter. Testing to be performed includes, blood gas/pH, sodium, potassium, glucose, ionized calcium and hematocrit (Chem 8 cartridge).

Motion to approve: Dr. McDonald
Second: Ms. Jenkins

Ms. England brought to the Board's attention the physical separation of Skyline and it's Madison Campus with two separate and distinct addresses in regard to Rule 1200-06-03-.02 (1)(b)(c) whereas (b) All laboratories performing tests must file a separate application for each laboratory address; And (c) Laboratories within a hospital that are located in contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.

There was discussion on this point of information and the determination by the Board was there were not two laboratories represented in this request since there is no laboratory at the Madison Campus thus one exemption for both locations was within the rule.

The chairman called for the vote on the motion:
In favor of the motion: six (6) Board members voted for the motion; one (1) Board member, Dr. Wilson, voted against the motion.

Motion approved.

**Centennial
Medical Center
Nashville, TN**

Molly Wynn, Point of Care Coordinator, requested a change in methodology for Troponin testing currently approved. The change in the exemption would be to permit Registered Nurses, Licensed Practical Nurses, Registered Radiologic Cardiac Invasive Specialists and Licensed EMTs to perform and report cardiac markers (Troponin) in the Emergency Department, the Chest Pain Emergency Department and the Cardiac Cath Lab utilizing the I-Stat. The previous methodology was the Stratus Vista.

Motion to approve: Dr. McDonald

Second: Dr. Papuchis

Motion approved

**Southern
Tennessee Medical
Center
Winchester, TN**

Sandy Campbell, Laboratory Manager, requested a new exemption for cath lab nurses (Registered Nurses or Licensed Practical Nurses) to perform blood oximetry using the Avoximeter 4000 in the Cath Lab.

Motion to approve: Dr. McDonald

Second: Ms. Jenkins

Motion approved

**Methodist
University
Hospital
Memphis, TN**

(Dr. Joyner and Dr. Wilson recused)

Harriet Bateman, Point of Care Coordinator, requested an exemption for Pefusionists to perform and report activated clotting testing (ACTs) and to monitor quantitative heparin utilizing the HMS Plus System (Hepcon) and methodologies in the cardiovascular surgery unit.

(Attorney Layden, as a point of order, informed the chair that with the recusal of Dr. Joyner and Dr. Wilson, there was no longer a quorum of the Board present and thus this exemption could not be acted upon. It was decided to determine if there was sufficient cause for the Board member(s) to recuse themselves. Upon discussion, it was determined there was no conflict of interest. Dr. Wilson returned to the discussion and a quorum of the Board was reestablished).

The request for exemption was reviewed again by the chairman.

Motion to approve: Dr. McDonald

Second: Dr. Papuchis

Motion approved

**Wellmont Bristol
Regional Hospital
Bristol, TN**

Richard Doyle, Point of Care Coordinator for Wellmont Holston Valley Medical Center representing Carol Stevenson POCC for Wellmont Bristol Regional Hospital, requested a change in methodology from the Gem 3000 to the Gem 4000. Exemption requested because of a change in methodology only in the testing of hemoglobin and hematocrit on the GEM 4000. The method on the GEM 3000 is a measured hematocrit and

calculated hemoglobin. With the GEM 4000 the hemoglobin is a measured analyte and the hematocrit is calculated. All other analytes on both instruments are the same methodology

The request is for perfusionists, certified anesthesiology techs and licensed registered nurses working in surgery and cardiovascular areas be allowed to continue performing tests for which an exemption on the GEM 3000 for this category of personnel and these tests is presently granted.

Move for approval: Dr. Papuchis
Second: Dr. Joyner

Motion approved.

**Wellmont Holston
Valley Medical
Center
Kingsport, TN**

Richard Doyle, Point of Care Coordinator for Wellmont Holston Valley Medical Center, requested a change in methodology from the Gem 3000 to the Gem 4000. Exemption requested because of a change in methodology only in the testing of hemoglobin and hematocrit on the GEM 4000. The method on the GEM 3000 is a measured hematocrit and calculated hemoglobin. With the GEM 4000 the hemoglobin is a measured analyte and the hematocrit is calculated. All other analytes on both instruments are the same methodology

The request is for perfusionists, respiratory therapists, licensed practical nurses and licensed registered nurses working in surgery, cardiac surgery and cardiac intensive care areas be allowed to continue performing tests for which an exemption on the GEM 3000 for this category of personnel and these tests is presently granted.

Move for approval: Dr. McDonald
Second: Ms. Jenkins

Motion approved.

**Kindred
Healthcare
Nashville, TN**

Dianna Denton, POCC for Kindred Healthcare, requested a new exemption for the use of I-Stat Meters in patient care areas, using the Chem 8 cartridge by licensed Registered Nurses and Respiratory Therapists.

Motion to approve: Dr. McDonald
Second: Dr. Bullock

Motion approved

**UHS/LabCorp
Knoxville**

Mr. Crowe recused himself from the discussion and passed the gavel to the Vice-Chair, Dr. McDonald.

Ms. Deborah Headrick, Point of Care Coordinator, requested two exemptions:

1. To permit Registered Nurses to perform and report i-Stat Chem 8+ Cartridges, Pro Time Cartridges, CG8+ Cartridges, Troponin Cartridges utilized in the Emergency Department and Surgical Critical Care Units, and
2. To permit Registered Nurses to perform and report Aspirin Assay, P2Y12 Assay and IIb/IIIa Assay in the Interventional Radiology Unit, Cardiovascular Intensive Care Units and 8-East of the facility utilizing the Accumetrics VerifyNow instrument.

Motion to expand the Accumetrics to the additional areas requested, the I-Stat to RNs and the addition of the Troponin Assay to the I-Stat: Dr. Papuchis

Second: Ms. Jenkins

Motion approved

The gavel was returned to the Chairman, Mr. Crowe

The Chair called for a 15 minute break at 10:25 AM.

The Chair called the meeting back into session at 10:45 AM.

**Direct More Than Three (3) Labs
Rule 1200-6-3-.13(5) Medical Lab
Facilities:**

No requests were presented to the Board during the meeting.

**Discuss, review, and take action, if
needed, regarding but not limited
to the following:**

**Rule 1200-06-01:
Laboratory Supervision**

Ms. England asked for Board clarification regarding supervision in the laboratory, ie. One supervisor of record vs. the naming of several supervisors with none being named as the supervisor of record.

Moved that there be a reiteration of naming a supervisor of record rather than listing several supervisors: Dr. McDonald

Second: Dr. Joyner

After discussion, Dr. McDonald withdrew his motion and the Board stated their position that they support the Administrative office of the Medical Laboratory Board in its efforts to have a single communication point for each licensed laboratory for correspondence and communication.

**Lab Clerks in Physician
Offices**

Ms. England stated she had received the following inquiry: "There are laboratories placing clerks in physician's offices to process specimens. There is no testing being performed. They centrifuge, aliquot, complete paperwork and ship or send by courier. Specimens are referred back to clerk-supplier laboratory with a small percentage sent out of state. Is this a violation of any of the Board's rules regarding licensed laboratories?"

Dr. Clinton, representing Sonic Healthcare, was present to address the Board. Questions and/or points of clarification were:

1. How do these individuals fit under the category of preparatory personnel in the Tennessee regulations;
2. Do these clerks perform functions that would be defined as preparatory similar to those performed by preparatory personnel including which specimens and what part of the phase of testing are they allowed to complete, thus do they require competency assessment training as would other preparatory personnel involved in the pre-analytic phase of laboratory determinations?
3. Since the physician's office is performing venipunctures, charging and being reimbursed for same, are these preparatory activities included as a part of the venipuncture and thus included in the reimbursement that the physician is receiving?

(Dr. Joyner recused himself)

A detailed discussion regarding the questions and activities followed.

Attorney Layden interjected that the Board should enter into discussion and engage in questions, however they should refrain from voting or stating a position until such time as legal counsel has an opportunity to research

the issues more closely. There could be the filing of complaints if it is determined there is inappropriate conduct.

It was discussed that Rule 1200-06-03-.19 PREPARATORY PORTIONS OF LABORATORY TESTS, in its entirety, addresses questions (1) and (2) and if there are specific violations to these rules, a complaint should be submitted for investigation.

In regard to question (3), the Board hesitates to comment on or interpret Federal Regulations and specifically inducement as defined in the Starke legislation.

No action taken.

**Patient Test Management:
Laboratory Reports**

Dr. Scott McCullough was present to address the Board regarding policy decisions dating back to 2004, specifically patient test management and laboratory reports.

Dr. McCullough's concern was that Board policy* regarding the prohibition of clinical laboratories providing results of testing procedures performed in that laboratory directly to any physician's patient, appeared to interfere with his relationship as a physician with patients and limited his scope of practice as a pathologist. Furthermore, Dr. McCullough contended that the policy directly interposed the Medical Laboratory Licensing Board between the physician and the patient to prohibit legitimate medical communication. His conclusion was that such an interpretation is not appropriate and it likely violated the policies of the Board of Medical Examiners.

After discussion, it was stated that this Board would defer any action until the Board of Medical Examiners could meet and make their determination.

No action taken.

*(*The statutory authority basis for the policy is contained in TCA §68-29-121(b), §68-29-126(5) and §68-29-129(5))*

The Chair called for a break at 12:20 PM

The Chair called the meeting back into session at 12:40 PM

Discussion of the Rules: As a result of action taken in the January meeting, the
Competency vs. Licensure; Board had requested that legal counsel develop possible
rule revisions in regard to competency vs. licensure.

No action taken

The Chair called for a Break at 2:00 PM

The Chair called the meeting back in session at 2:15 PM

Report from Previous Rule Governing Rules-General Rules Governing Medical
Making Hearing Laboratories, the Board had a previous rule making
1200-06-03-.12 hearing relative to reportable diseases. The information
went to the Attorney General's office. Upon their
review it was suggested the phrase be added: **Reports
and other** to our rule in order to be consistent with the
other rules from the Department of Health,
Communicable and Environmental Disease Service, so
that it is clear that laboratory directors have their
obligation to continue the reporting and submission of
cultures. The list on the website would dictate which
microorganisms must be submitted to the department.

A roll call vote was needed to ratify.

Motion to accept the amendment: Ms. Arnott
Second: Dr. Bullock

Dr. Joyner	Aye
Ms. Jenkins	Aye
Mr. Crowe	Aye
Dr. Wilson	Aye
Dr. McDonald	Aye
Dr. Papuchis	Aye
Dr. Bullock	Aye
Ms. Arnott	Aye

Motion to accept approved by a majority of the Board
present

Additions/Deletions to the Board's Nothing to present
Waived Test List

Receive reports and/or requests

Board Director's Report Ms. England reported the following:

Board meeting dates for 2011 are listed in the report.

There was one facility closure in June.

The Board position of Hospital Administrator has been filled.

Program statistics are listed in the report.

Motion to accept report: Dr. McDonald

Second: Dr. Papuchis

Report accepted.

Office of General Counsel

There are two open cases, one was the consent order presented. The office is working on the Rules.

Motion to accept report: Dr. Joyner

Second: Dr. Papuchis

Report accepted.

Quarterly Financial Report

Motion to accept report as presented: Ms. Jenkins

Second: Ms. Arnott

Motion approved

**Bureau of Investigations
(BIV) Report**

**Juanita Stone: Disciplinary
Coordinator**

Ms. England presented the report, first half 2010, in the absence of Ms. Stone.

The following actions were reported to board members:

Currently open Complaints: Three (3)

Total Closed Complaints: Zero (0)

Motion to accept report as presented: Dr. Bullock

Second: Dr. Papuchis

The report was accepted as presented

**Reports/Discussion Regional
Surveyors**

ETRO Report

East TN Regional Office: Julia Daniels

Unsatisfactory/ Unsuccessful Proficiency Testing:

The East Tennessee Regional Office reported Eight (8) unsuccessful proficiency testing events for the second quarter of 2010. An acceptable plan of action was received from all laboratories involved.

Complaint Investigations:

The East Tennessee Regional Office conducted Zero (0) investigation(s), substantiated, for the second quarter of 2010.

MTRO Report

Middle TN Regional Office: Karen Hargrove

Unsatisfactory/Unsuccessful Proficiency Testing:

The Middle Tennessee Regional Office reported Zero (0) unsuccessful proficiency testing events for the first quarter of 2010. (Two out of Three PT Events or Two in a Row)

Licensed laboratories with a second occurrence of unsuccessful proficiency testing events for the second quarter of 2010. (three out of four or three in a row): zero (0).

Complaint Investigation:

The Middle Tennessee Regional Office conducted Zero (0) complaint investigation(s) for the second quarter of 2010. There was one (1) CLIA generated complaint.

WTRO Report

West Tennessee Regional Office: Mary Hamblin

Unsatisfactory /Unsuccessful Proficiency Testing:

The West Tennessee Regional Office reported Zero (0) unsuccessful proficiency testing events for the second quarter of 2010. (Two out of Three PT Events or Two in a Row)

Licensed laboratories with a second occurrence of unsuccessful proficiency testing events for the second quarter of 2010. (three out of four or three in a row): zero (0).

Complaint Investigations:

There was zero (0) complaint investigations conducted for the second quarter of 2010.

Motion to accept regional surveyor's report as presented: Dr. Bullock

Second: Dr. Papuchis

Report accepted as presented

Board Ratification of Laboratory Initial License

Signature Medical Laboratory Mt. Juliet, TN	Medical Director:	Thomas G. Westermeier, MD Anatomic/Clinical Pathology
	Specialties:	Hematology, Clinical Chemistry, Urinalysis, hCG
	Surveyor:	Onezean Otey, Jr. Middle Tn. Regional Surveyor
	Motion to ratify initial licensure:	Dr. McDonald
	Second:	Ms. Jenkins
	Motion to ratify approved	

Approve Licensure for Laboratory Director

Alejandro Molinelli, Ph.D Director of Chemistry Memphis, TN 38105	Initial applicant as Director of Chemistry	
	1997-BS Biology, University of Puerto Rico	
	2003-MS Biochemistry, University of Puerto Rico	
	2006-Ph.D Toxicology, University of North Carolina, Chapel Hill	
	2006-2008 Postdoctoral Fellowship in Clinical Chemistry, University of Washington, Seattle, WA. Program was accredited by the Commission on Accreditation in Clinical Chemistry.	
	Certified with the National Registry of Certified Chemists.	
	All qualifying documents are present in the file.	
	Move to approve license: Dr. McDonald	
	Second: Dr. Joyner	
	License approved	

Other Business

C.L.E.A.R. Conference	Motion to approve funds for Board attendance: Ms. Jenkins
	Second: Ms. Arnott
	Counsel passed out a draft policy statement on FISH for review and for discussion at next meeting.

Statement of Next Meeting

The next Board Meeting will be October 14, 2010, and
will begin at 9 AM CDT in the Iris Room, Ground
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Floor, Heritage Place, 227 French Landing, Metro Center, Nashville, TN. 37243.

Record of Adjournment

With no further business to discuss, the meeting was adjourned at 2:45 PM CDT on a motion properly presented by Dr. McDonald seconded by Dr. Papuchis.